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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,456		Vered Hornik	2254-031	2896

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/644,456

Applicant(s)

HORNIK ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/01/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 29-39 is/are pending in the application.
- 4a) Of the above claim(s) 7-11, 31, 33-36 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 29, 30, 32, 37, 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

Amendment filed 10/01/2003 is acknowledged. Claims 1-11,29-39 are pending. Claims 1,32 are amended. Claims 7-11,31,33-36 and 39 remain withdrawn from consideration. Claims 1-6, 29,30, 32,37,38 are under consideration.

Information Disclosure Statement

Applicants' Information Disclosure Statement filed 10/14/2003 and 10/01/2003 have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

In regard to foreign language documents, the information disclosure statements fail to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56[©] most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

In regard to English language references, although a concise explanation of the relevance of information is not required for English language information, applicants

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are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more is highly relevant to patentability. M.P.E.P. § 609. This statement is in accord with *dicta* from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), which states that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888. A cursory glance at the M.P.E.P. also provides more support for this position. In a subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp 948 (S.D. Fla. 1972) *aff'd* 479 F.2d 1338 (5th Cir 1974); [Molins]."

MPEP 2004.

Therefore, it is recommended that if any information that has been cited by Applicants in the previous disclosure statement, is known to be material for

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patentability as defined by 37 CFR 1.56, applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

Claim Rejections - 35 USC § 112, first paragraph.

Claims 29,37 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 29,37 introduce new matter as they present a new generic formula (which blends together formulas 3 and 4) which encompass genus not described in the application as filed.

Response to arguments

Applicant argues that the genus newly created in claims 29,37 is sufficiently described on page 13 of specification. Examiner disagrees. The specification does not describe peptides formed by bridging residues R2 and R5 (it is either R2 and R5 in formula 3, or R. and R5 in formula 4). The newly created genus encompasses species not encompassed by either formula 3 or 4, for example peptide wherein R. is Gln, R2 is Ala, R3 is (D)Bip, R4 is 4PyrAla, R5 is Orn, and R6 is Abu.

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Claim Rejections - 35 USC § 102 and 103.

Claims 1-6,32 are rejected under 35 U.S.C. 102(b) as anticipated by Gilon et al (EP 564739; reference AZ in IDS filed 10/14/2003)

Generic claims 1-6,32 are drawn to broadly defined backbone cyclized peptide. As such the claims read on any cyclic peptide satisfying the minimum structural requirements recited in the claims. The claims as amended require the bridge to contain methylene links (CH₂)_m and (CH₂)_n. Consequently, rejection over Freidinger (US 4,235,886) made in the previous Office action is withdrawn and replaced with rejection over Gilon et al (EP 564739) which is used as another exemplary reference.

Gilon et al (EP 564739) teach backbone cyclized peptides which have at least five residues and comprise a building unit that contains a nitrogen atom connected to a bridging group. See, e.g., claims 1-9. The referenced compounds satisfy structural requirements of instant claims 1-4. In regard to claims 5,6, the claim limitation "derived" is read as any derivation of peptide structure (e.g., substitution) which may result, for example, in the referenced peptides. In regard to the functional limitation, even if a reference does not teach the functional limitation of the peptide, such a limitation would be inherent in the peptide since it meets the structural limitations of the claim. A reference which is silent about a claimed invention's feature is inherently

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anticipatory if the missing feature is necessarily present in that which is described in the reference. In re Oelrich, 212, USPQ 323 (CCPA 1981). Where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 15USPQ2d 1655, 1658 (Fed. Cir., 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Conclusion.

As previously indicated, claims 30,38 are novel and unobvious over the prior art of record or any combination thereof, and are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

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Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

February 4, 2004

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written below the printed name.